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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

JULIE A. HIMBER,

Plaintiff,

vs.

JOHNSON & JOHNSON; and JANSSEN PHARMACEUTICALS, INC.,

Defendants.

Case No. 2:15-cv-6198

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. **Strict Liability**
2. **Product Liability – Failure to Warn**
3. **Negligence**
4. **Breach of Express Warranty**
5. **Breach of Implied Warranty**
6. **Fraud**
7. **Negligent Misrepresentation**
8. **Fraudulent Concealment**

Plaintiff, Julie A. Himber ("Plaintiff"), by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (collectively, "Defendants"), and alleges as follows:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the

design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drug Levaquin® (also known as levofloxacin). Levaquin® in any of its forms shall herein be referred to as "Levaquin."

2. Plaintiff maintains that Levaquin is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

PARTIES

3. Plaintiff, Julie A. Himber, is a natural person and a resident and citizen of Los Angeles County, California. Plaintiff brings this action for personal injuries sustained by the use of Levaquin. As a direct and proximate result of being prescribed and ingesting Levaquin, Plaintiff developed irreversible peripheral neuropathy.

4. Defendant Johnson & Johnson is a New Jersey corporation that has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

5. Defendant Johnson & Johnson has transacted and conducted business within the State of California.

6. Defendant Johnson & Johnson has derived substantial revenue from goods and products used in the State of California.

7. Defendant Johnson & Johnson expected or should have expected its acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

8. Defendant Johnson & Johnson was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

9. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation which has its principal place of business in New Jersey.

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10. Defendant Janssen Pharmaceuticals, Inc. has transacted and conducted business within the State of California.

11. Defendant Janssen Pharmaceuticals, Inc. has derived substantial revenue from goods and products used in the State of California.

12. Defendant Janssen Pharmaceuticals, Inc. expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

13. At all times material hereto, Defendant Janssen Pharmaceuticals, Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

14. Defendant Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson.

15. Defendants are authorized to do business in California and derive substantial income from doing business in this state.

16. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with the State of California, thus invoking the benefits and protections of its laws.

17. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture and/or distribute Levaquin, with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

18. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendants are all either incorporated and/or have their principal place outside of the state in which the Plaintiff resides.

19. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

20. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 in that Defendants conduct business here and are subject to personal jurisdiction in this

District. Furthermore, Defendants sell, market and/or distribute Levaquin within the State of California and this District.

FACTUAL ALLEGATIONS

21. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the pharmaceutical drug Levaquin.

22. Plaintiff was prescribed Levaquin in July 2008 and used it as directed.

23. Levaquin is a broad-spectrum fluoroquinolone antibiotic used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.

24. Levaquin is a member of the quinolone class of antibiotics. Quinolones are divided into four generations based on their spectrum of antimicrobial activity.

25. The 1st generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

26. Twenty years later, in the early 1980s, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called 2nd generation quinolones included Noroxin® (norfloxacin), Cipro® (ciprofloxacin), Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

27. Fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the United States market due to intolerable adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam®

(sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

28. Levaquin was approved by the United States Food and Drug Administration (hereinafter, the "FDA") on December 20, 1996, for use in the United States, and is the brand name for the antibiotic levofloxacin.

29. In 2003, after generic versions of Cipro® (a competing fluoroquinolone antibiotic) went on the market, Levaquin became the number one prescribed fluoroquinolone in the United States.

30. In 2006, after generic versions of Zithromax, a highly popular macrolide antibiotic, went on the market, Levaquin became the number one prescribed antibiotic in the world.

31. In 2007, Levaquin was ranked 37 of the top 200 drugs that were prescribed in the United States.

32. In 2007, Levaquin was ranked 19th in world sales of prescribed drugs.

33. In 2007, Levaquin accounted for 6.5% of Defendant Johnson & Johnson's total revenue, generating $1.6 billion in revenue, an 8% increase over the previous year.

34. Defendant Janssen Pharmaceuticals, Inc. indicates on its website that "[i]n a large number of clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections."

35. However, the scientific evidence has established a clear association between Levaquin and an increased risk of long-term and sometimes irreversible peripheral neuropathy.

36. Defendants knew or should have known that Levaquin is associated with an increased risk of developing irreversible peripheral neuropathy.

37. Defendants failed to appropriately and adequately inform and warn Plaintiff and Plaintiff's prescribing physicians of the serious and dangerous risks

associated with the use of Levaquin concerning peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

38. The warning label for Levaquin during the period from September 2004 through August 2013 misled Plaintiff and Plaintiff's treating physicians by incorrectly advising patients and physicians that peripheral neuropathy associated with Levaquin was "rare" and in any case could be avoided by discontinuing the drug upon the onset of certain symptoms. The truth, however, is that the onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug will not ensure that the peripheral neuropathy is reversible.

39. Though this injury can be significant and debilitating, the language regarding the "rare" risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Levaquin label; the language was in no way highlighted for the benefit of prescribing physicians and patients.

40. Additionally, Defendants failed to disseminate a "Dear Doctor" letter to physicians concerning the label change or the risk of irreversible peripheral neuropathy, and Defendants failed to disclose this serious and dangerous effect when promoting Levaquin to physicians.

41. Despite their knowledge that Levaquin was associated with an elevated risk of permanent nerve damage, Defendants' promotional campaign was focused on Levaquin's purported "safety profile."

42. As early as 1992, there was evidence of the association between fluoroquinolones and peripheral neuropathy. Dr. Aoun from the Infectious Diseases Clinic and Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a letter to the editor of the Lancet raising concerns about a 37-year old

patient who developed peripheral neuropathy after taking fluoroquinolones.[1]

43. Four years later, Karin Hedenmalm and Olav Spigset published "Peripheral sensory disturbances related to treatment with fluoroquinolones" based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.[2]

44. In 2001, Jay S. Cohen published a research study in the United States entitled "Peripheral Neuropathy Associated with Fluoroquinolones."

45. The Cohen paper studied forty-five (45) patients and expressed concerns over a link between permanent peripheral neuropathy and fluoroquinolones.[3]

46. In 2002 and 2003, Defendants were put on notice that numerous reports had been submitted to the FDA's Adverse Event Reporting System that identified fluoroquinolone users who had developed disabling peripheral neuropathy that persisted long after the drug had been discontinued.

47. A scientific review by the FDA of the adverse events in the FDA Adverse Event database in 2003 concerning Levaquin and other fluoroquinolones revealed numerous reports of long-term peripheral neuropathy.

48. In 2004, the Levaquin label was amended to include the following statement regarding peripheral neuropathy in the Warnings section:

> **Peripheral Neuropathy:** Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been

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[1] Aoun M., Jacquy C, Debusscher L, Bron D, Lehert M, Neol P, et al. Peripheral neuropathy associated with fluoroquinolones (letter). Lancet. 1992;340:127.

[2] Hedenmalm, K. and Spigset, O. Peripheral sensory disturbances related to treatment with fluoroquinolones. J Antimicrob Chemother 1996;37(4):831-7.

[3] Cohen, JS. Peripheral neuropathy associated with fluoroquinolones. Ann Pharmacother 2001;35:1540. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy, and concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information." *Id.*

> reported in patients receiving quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition.

49. Thus, rather than warning patients and physicians that the use of Levaquin may result in permanent nerve damage, Defendants instead adopted a warning that misleadingly indicated such damage was rare and, in any event, could be avoided by simply discontinuing the drug upon the onset of certain symptoms.

50. Defendants' failure to adequately warn physicians resulted in (1) patients receiving Levaquin instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which Plaintiff presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with Levaquin.

51. The failure of Defendants to include appropriate warnings in the label, as published to the medical community, also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

52. Despite Defendants' knowledge and failure to adequately warn Plaintiff and Plaintiff's physicians of the above, Defendants continue to market Levaquin as a first line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections, conditions for which many other safer antibiotics are available.

53. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the existing warnings regarding peripheral nerve damage were inadequate. On August 15, 2013, an updated warning was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included in the Levaquin label, and which removed the statement that nerve damage occurred only in "rare" cases:

> Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including Levaquin. Symptoms may occur soon after initiation of Levaquin and may be irreversible. Levaquin should be discontinued immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.

54. According to a study conducted by Ayad Ali, RPh, PhD, and published in *Annals of Epidemiology* in January 2014, between 1997 and 2012, there were 539 reports of peripheral neuropathy among 46, 257 adverse event reports submitted for fluoroquinolone antibiotics to the FDA's Adverse Event Reporting System.[4] A pharmacovigilance analysis of this data further underscored the link between systemic exposure to fluoroquinolones and peripheral neuropathy, and showed a potential association with more severe forms of nerve damage.[5] The Ali paper also detailed the presence of strong safety signals dating back to at least 2005 regarding the potential for Levaquin and other fluoroquinolones to cause long-term, disabling peripheral neuropathy.

55. An epidemiologic study published in the August 2014 online edition of *Neurology* provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.[6] The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI: 1.49-2.27), with current users having the highest risk of exposure (RR = 2.07, 95% CI: 1:56-2.74).

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[4] Ali, A.K. Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis. Annals Epidemiol. 2014:24(4):279-85.

[5] *Id.*

[6] Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. Neurology 2014; Epub 2014 Aug 22.

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EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

56. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

57. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Levaquin.

58. As a result of Defendants' actions, Plaintiff and, upon information and belief, Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

59. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Levaquin. Defendants were under a duty to disclose the true character, quality, and nature of Levaquin because this was non-public information over which Defendants had and continues to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

60. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug,

notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the discovery rule and/or the doctrine of fraudulent concealment from relying upon any statute of limitations.

COUNT I

[Strict Liability]

61. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

62. Levaquin was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Levaquin failed to warn of the dangerous risks posed by Levaquin, including the risk of developing irreversible peripheral neuropathy.

63. At all times alleged herein, Levaquin was defective and Defendants knew that Levaquin was to be used by consumers without inspection for defects. Moreover, Plaintiff, Plaintiff's prescribing physicians, and Plaintiff's health care providers neither knew nor had reason to know at the time of Plaintiff's use of Levaquin of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

64. At all times alleged herein, Levaquin was prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

65. The design of Levaquin was defective in that the risks associated with using Levaquin outweighed any benefits of the design. Any benefits associated with the use of Levaquin were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or

more effectively reach similar results but without the increased risk of developing irreversible peripheral neuropathy.

66. The defect in design existed when the product left Defendants' possession.

67. At the time Levaquin left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting Levaquin.

68. As a result of Levaquin's defective condition, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT II

[Product Liability – Failure to Warn]

69. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

70. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Levaquin, and through that conduct have knowingly and intentionally placed Levaquin into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff who ingested it.

71. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Levaquin to Plaintiff and to Plaintiff's prescribing physicians. Additionally, Defendants expected the Levaquin that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Levaquin did in fact reach – prescribing physicians and consumers, including Plaintiff and Plaintiff's prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

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72. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Plaintiff. The defective condition of Levaquin was due in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.

73. This defect caused serious injury to Plaintiff, who used Levaquin in its intended and foreseeable manner.

74. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

75. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

76. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Levaquin, namely irreversible peripheral neuropathy.

77. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Levaquin caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from Levaquin use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

78. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

79. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

80. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

81. Had Defendants properly disclosed the risks associated with Levaquin, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using Levaquin.

82. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT III

[Negligence]

83. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

84. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Levaquin.

85. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

86. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not

limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Levaquin;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Levaquin's dangerous and defective characteristics;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;

d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;

e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

f) In failing to perform appropriate pre-market testing of the subject product;

g) In failing to perform appropriate post-market surveillance of the subject product;

h) In failing to adequately and properly test Levaquin before and after placing it on the market;

i) In failing to conduct sufficient testing on Levaquin which, if properly performed, would have shown that Levaquin had the serious side effect of causing irreversible peripheral neuropathy;

j) In failing to adequately warn Plaintiff and Plaintiff's healthcare providers that the use of Levaquin carried a risk of developing irreversible peripheral neuropathy;

k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of Levaquin; and

l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from Levaquin ingestion as described herein.

87. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

88. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT IV

[Breach of Express Warranty]

89. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

90. Before Plaintiff was first prescribed Levaquin and during the period in which Plaintiff used Levaquin, Defendants expressly warranted that Levaquin was safe.

91. Levaquin did not conform to these express representations because Levaquin was not safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.

92. As a direct and proximate result of this wrongful conduct, Plaintiff was injured as described above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT V

[Breach of Implied Warranty]

93. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

94. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold Levaquin, and prior to the time that it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that the subject product was of merchantable quality and safe and fit for the use for which it was intended.

95. Plaintiff, individually and through Plaintiff's prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

96. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

97. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after Plaintiff used it.

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98. Contrary to the implied warranty for the subject product, Levaquin was not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

99. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VI

[Fraud]

100. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

101. Defendants made misrepresentations to Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry regarding the safety and effectiveness of Levaquin and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Levaquin.

102. Defendants made misrepresentations and actively concealed adverse information when Defendants knew, or should have known, that Levaquin had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians, and the healthcare industry generally. Specifically, Defendants actively concealed from Plaintiff, Plaintiff's prescribing physicians, the

health care industry, and the consuming public that:

(a) Since at least 1996, Defendant Johnson & Johnson and/or its predecessors were in possession of data demonstrating that Levaquin increases the risk of irreversible peripheral neuropathy;

(b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Levaquin before and after their product launch;

(c) Levaquin was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Levaquin increases the risk of irreversible peripheral neuropathy.

103. The misrepresentations and/or active concealments were perpetuated directly and/or indirectly by Defendants.

104. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, Plaintiff’s prescribing physicians, and the healthcare industry.

105. Defendants made these false representations with the intent or purpose that Plaintiff, Plaintiff’s prescribing physicians, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.

106. At all times herein mentioned, neither Plaintiff nor Plaintiff’s physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, Plaintiff’s physicians would not have prescribed and Plaintiff would not have taken the subject product.

107. Plaintiff, Plaintiff’s prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants’ misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of

Levaquin that Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of Levaquin. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

108. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with Levaquin in a timely manner.

109. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Levaquin as a treatment.

110. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Levaquin and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VII

[Negligent Misrepresentation]

111. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

112. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry the safety and effectiveness of Levaquin and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and

dangers posed by Levaquin.

113. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that Levaquin had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996, Defendant Johnson & Johnson and/or its predecessors were in possession of data demonstrating that Levaquin increases the risk of irreversible peripheral neuropathy;

(b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Levaquin before and after their product launch;

(c) Levaquin was not fully and adequately tested by Defendants and/or their predecessors for the risk of developing irreversible peripheral neuropathy; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Levaquin increases the risk of irreversible peripheral neuropathy.

114. The negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

115. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry.

116. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, Plaintiff's prescribing

physicians, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.

117. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, Plaintiff's physicians would not have prescribed and Plaintiff would not have taken the subject product.

118. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Levaquin and relied on the absence of information regarding the dangers of Levaquin which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

119. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with Levaquin in a timely manner.

120. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Levaquin as a treatment.

121. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Plaintiff ingested Levaquin and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

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COUNT VIII

[Fraudulent Concealment]

122. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

123. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false, and/or with reckless disregard for the truth or falsity of such material representations with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on such material representations.

124. Plaintiff and Plaintiff's prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiff was injured as a direct and proximate result.

125. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, Plaintiff's prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on Defendants' misrepresentations. Plaintiff and Plaintiff's prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiff was injured as a result.

126. At all times herein mentioned, Defendants had a duty to Plaintiff, Plaintiff's prescribing physicians, and the general public to accurately inform them of risks associated with Levaquin because Defendants, as the manufacturer and/or distributor of the subject product, were in a position of superior knowledge and judgment regarding any potential risks associated with Levaquin.

127. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Levaquin at issue in this lawsuit, said breach or breaches constituting fraud because of the propensity to deceive others or

constitute an injury to public interests or public policy.

128. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of Levaquin to increase sales of the drug at the expense of informing Plaintiff that, by ingesting Levaquin, Plaintiff was placed at a significantly-increased risk of developing irreversible peripheral neuropathy.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

PUNITIVE DAMAGES

129. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

130. At all times material hereto, Defendants knew or should have known that Levaquin was inherently dangerous with respect to the risk of irreversible peripheral neuropathy.

131. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Levaquin.

132. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the subject product.

133. At all times material hereto, Defendants knew and recklessly disregarded the fact that Levaquin causes the chronic illness irreversible peripheral neuropathy.

134. Notwithstanding the foregoing, Defendants continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effect.

135. Defendants knew of their subject product's lack of warnings regarding the risk of irreversible peripheral neuropathy, but they intentionally concealed and/or

recklessly failed to disclose that risk and continued to market, distribute, and/or sell Levaquin without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Levaquin.

136. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable Plaintiff to weigh the true risks of using Levaquin against its benefits.

137. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

138. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for Levaquin;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) For such further relief as this Court deems necessary, just, and proper.

DATE: August 14, 2015

Respectfully submitted,
HEARD ROBINS CLOUD LLP

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DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

DATE: August 14, 2015

Respectfully submitted,
HEARD ROBINS CLOUD LLP

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